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Atty. Dkt. No. 029849-0206

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Vaillant and Juteau  
Title: ANTIVIRAL  
OLIGONUCLEOTIDES  
TARGETING HBV  
Appl. No.: 10/661,088  
Filing Date: 09/12/2003  
Examiner:  
Art Unit: 1614

**CERTIFICATE OF MAILING**

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DIANE GARCIA  
(Printed Name)

Diane Garcia  
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11-23-04  
(Date of Deposit)

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop Amendment-IDS  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to OG Notice dated August 5, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

Applicants submit herewith on Form PTO/SB/08 a listing of the documents cited by or submitted to the U.S. PTO in related application Serial No. 10/661,403 also filed 09/12/2003. As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were

previously submitted to the United States Patent & Trademark Office in that application and are on file with the USPTO.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

#### **TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

#### **RELEVANCE OF EACH DOCUMENT**

The relevance of the foreign-language document is explained in the related application.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even

entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit  
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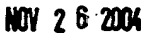
Respectfully submitted,

Date November 23, 2004

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By 

David P. Lentini  
Attorney for Applicant  
Registration No. 33,944



Approved for use through 10/31/2002. OMB 0651-0031

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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	13
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**Complete if Known**

<b>Application Number</b>	10/661,088
<b>Filing Date</b>	09/12/2003
<b>First Named Inventor</b>	Andrew Vaillant et al.
Group Art Unit	1614
<b>Examiner Name</b>	
<b>Attorney Docket Number</b>	029849-0206

[illegible][illegible]

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A2	AGRAWAL and KANDIMALLA, "Antisense and/or Immunostimulatory Oligonucleotide Therapeutics," <i>Current Cancer Drug Targets</i> 1:197-209 (2001)	
	A3	ALLEN and CHONN, "Large Unilamellar Liposomes with Low Uptake into the Reticuloendothelial System," <i>FEBS Letters</i> 223(1):42-46 (1987)	
	A4	ARCHAMBAULT, <i>et al.</i> , "Phosphorothioate oligonucleotides inhibit the replication of lentiviruses and type D retroviruses, but not that of type C retroviruses," <i>Arch Virol</i> 139:97-109 (1994)	

Examiner  
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<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached

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Examiner Name			
Sheet	2	of	13
		Attorney Docket Number	029849-0206

## NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A5	BERKOW, <i>et al.</i> , "Nonsteroidal Anti-Inflammatory Drugs (NSAIDs)," <i>The Merck Manual of Diagnosis and Therapy</i> , 15 <sup>th</sup> ed., 2499-2506 and 46-49 (1987)	
	A6	BLUME and CEVC, "Liposomes for the sustained drug release in vivo," <i>Biochimica et Biophysica Acta</i> 1029:91-97 (1990)	
	A7	BRUNTON, "Section VI Drugs Affecting Gastrointestinal Function," <i>The Pharmacological Basis of Therapeutics</i> 9(38):934-935 (1996)	
	A8	BUUR, <i>et al.</i> , "Penetration of 5-Fluorouracil and Prodrugs Across the Intestine of the Albino Rabbit: Evidence for Shift in Absorption Site from the Upper to the Lower Region of the Gastrointestinal Tract by Prodrugs," <i>Journ. of Controlled Release</i> 14:43-51 (1990)	
	A9	CAMPBELL and REIN, "In Vitro Assembly Properties of Human Immunodeficiency Virus Type 1 Gag Protein Lacking the p6 Domain," <i>Journ. of Virol.</i> 73:2270-2279 (1999)	
	A10	CEVC, <i>et al.</i> , "Ultraflexible vesicles, Transfersomes, have an extremely low pore penetration resistance and transport therapeutic amounts of insulin across the intact mammalian skin," <i>Biochimica et Biophysica Acta</i> 1368:201-215 (1998)	
	A11	CHENG, <i>et al.</i> , "Interactions Between Single-Stranded DNA Binding Protein and Oligonucleotide Analogs with Different Backbone Chemistries," <i>Journ. Mol. Recognition</i> 10:101-107 (1997)	
	A12	CONSTANTINIDES, <i>et al.</i> , "Formulation and Intestinal Absorption Enhancement Evaluation of Water-in-Oil Microemulsions Incorporating Medium-Chain Glycerides," <i>Pharmaceutical Res.</i> 11:1385-1390 (1994)	
	A13	CROOKE, <i>et al.</i> , "Pharmacokinetic Properties of Several Novel Oligonucleotide Analogs in mice," <i>Journ. Pharm. and Experm. Therap.</i> 277(2):923-937 (1996)	
	A14	CROOKE, S., "Progress in Antisense Technology: The End of the Beginning," <i>Meth. in Enzym.</i> 313:3-45 (1999)	

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	A15	Du PLESSIS, <i>et al.</i> , "Topical Delivery of Liposomally Encapsulated Gamma-Interferon," <i>Antivir. Res.</i> 18:259-265 (1992)	
	A16	EL-HARIRI, <i>et al.</i> , "The Mitigating Effects of Phosphatidylcholines on Bile Salt- and Lysophosphatidylcholine-induced Membrane Damage," <i>J. Pharm. Pharmacol.</i> 44:651-654 (1992)	
	A17	ENGLISH and GAUSS, "Chemically Modified Oligonucleotides as Probes and Inhibitors," <i>Angewandte Chemie</i> 30(6):613-722 (1991)	
	A18	FENG, <i>et al.</i> , "Reversible Binding of Recombinant Human Immunodeficiency Virus Type 1 Gag Protein to Nucleic Acids in Virus-Like Particle Assembly In Vitro," <i>Journ. of Virol.</i> 76(22):11757-11762 (2002)	
	A19	FENNEWALD, <i>et al.</i> , "Inhibition of herpes simplex virus in culture by oligonucleotides composed entirely of deoxyguanosine and thymidine," <i>Antiviral Res.</i> 26:37-54 (1995)	
	A20	GABIZON, <i>et al.</i> , "Liposome formulations with prolonged circulation time in blood and enhanced uptake by tumors," <i>Proc. Natl. Acad. Sci. USA</i> 85:6949-6953 (1988)	
	A21	GOA, <i>et al.</i> , "Effect of Phosphorothioate Homo-oligodeoxynucleotides on Herpes Simplex Virus Type 2-induced DNA Polymerase," <i>Journ. of Biol. Chem.</i> 264(19):11521-11526 (1989)	
	A22	GAO, <i>et al.</i> , "Inhibition of Herpes Simplex Virus Type 2 Growth by Phosphorothioate Oligodeoxynucleotides," <i>Antimicrobial Agents and Chemotherapy</i> 34(5):808-812 (1990)	

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	A23	HIGUCHI, <i>et al.</i> , "Particle Phenomena and Course Dispersions," <i>Remington's Pharmaceutical Sciences</i> 21:301-329 (1985)		
	A24	HO, <i>et al.</i> , "Preparation of Microemulsions Using Polyglycerol Fatty Acid Esters as Surfactant for the Delivery of Protein Drugs," <i>Journ. of Pharm. Sci.</i> 85:138-143 (1996)		
	A25	HU, <i>et al.</i> , "Topical delivery of cyclosporine A from non-ionic liposomal systems: an <i>in vivo/in vitro</i> correlation study using hairless mouse skin," <i>S.T.P. Pharma Sciences</i> 4(6):466-469 (1994)		
	A26	ILLUM and DAVIS, "The organ uptake of intravenously administered colloidal particles can be altered using a non-ionic surfactant (Poloxamer 338)," <i>FEBS</i> 1212 167:79-82 (1984)		
	A27	INAGAWA, <i>et al.</i> , "Inhibition of human immunodeficiency virus type 1 replication by P-stereodefined oligo (nucleoside phosphorothioate)s in a long-term infection model," <i>FEBS Lett.</i> 528:48-52 (2002)		
	A28	JAIRATH, <i>et al.</i> , "Inhibition of respiratory syncytial virus replication by antisense oligodeoxyribonucleotides," <i>Antiviral Res.</i> 33:201-213 (1997)		
	A29	JARRETT, H., "Affinity chromatography with nucleic acid polymers," <i>J. Chromotography</i> 618:315-339 (1993)		
	A30	KABANOV, <i>et al.</i> , "A new class of antivirals: antisense oligonucleotides combined with a hydrophobic substituent effectively inhibit influenza virus reproduction and synthesis of virus-specific proteins in MDCK cells," <i>FEBS Lett.</i> 259:327-330 (1990)		

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	A31	KANDIMALLA, <i>et al.</i> , "Effects of Phosphorothioate Oligodeoxyribonucleotide and Oligoribonucleotides on Human Complement and Coagulation," <i>Bioorg. &amp; Med. Chem. Lett.</i> 8:2103-2108 (1998)	
	A32	KEAN, <i>et al.</i> , "Inhibition of Herpes Simplex Virus Replication by Antisense Oligo-2'-O-methylribonucleoside Methylphosphonates," <i>Biochemistry</i> 34:14617-14620 (1995)	
	A33	KLIBANOV, <i>et al.</i> , "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes," <i>FEBS Lett.</i> 268:235-237 (1990)	
	A34	KLIMUK, <i>et al.</i> , "Enhanced Anti-Inflammatory Activity of a Liposomal Intercellular Adhesion Molecule-1 Antisense Oligodeoxynucleotide in an Acute Model of Contact Hypersensitivity," <i>Journ. of Pharm. &amp; Exper. Ther.</i> 292:480-488 (2000)	
	A35	KOOL, E., "Replacing the Nucleobases in DNA with Designer Molecules," <i>Acc. Chem. Res.</i> 35:936-943 (2002)	
	A36	LAVIGNE <i>et al.</i> , "Is antisense an appropriate nomenclature od design for oligodeoxynucleotides aimed at the inhibition of HIV-1 replication?" <i>AAPS PharmSci</i> , 4:1-11, 2002	
	A37	LEBEDEVA and STEIN, "Antisense Oligonucleotides: Promise and Reality," <i>Annu. Rev. Pharmacol. Toxicol.</i> 41:403-419 (2001)	
	A38	LEE, <i>et al.</i> , "Mucosal Penetration Enhancers For Facilitation of Peptide and Protein Drug Absorption," <i>Crit. Rev. in Ther. Drug Carrier Syst.</i> 8(2):91-192 (1991)	

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	A39	LERNER, <i>et al.</i> , "A Six-Month Trial of Valacyclovir in the Epstein-Barr Virus Subset of Chronic Fatigue Syndrome: Improvement in Left Ventricular Function," <i>Drugs of Today</i> 38(8): 549-561 (2002)	
	A40	LETSINGER, <i>et al.</i> , "Cholesteryl-conjugated oligonucleotides: Synthesis, properties, and activity as inhibitors of replication of human immunodeficiency virus in cell culture," <i>Proc. Natl. Acad. Sci. USA</i> 86:6553-6556 (1989)	
	A41	MANOHARAN, <i>et al.</i> , "Chemical Modifications to Improve Uptake and Bioavailability of Antisense Oligonucleotides," <i>Ann. N.Y. Acad. Sci.</i> 660:306-309 (1992)	
	A42	MANOHARAN, <i>et al.</i> , "Introduction of a Lipophilic Thioether Tether in the Minor Groove of Nucleic Acids for Antisense Applications," <i>Bioorg. &amp; Med. Chem. Letters</i> 3:2765-2770 (1993)	
	A43	MANOHARAN, <i>et al.</i> , "Cholic Acid-Oligonucleotide Conjugates for Antisense Applications," <i>Bioorg. &amp; Med. Chem. Lett.</i> 4:1053-1060 (1994)	
	A44	MANOHARAN, <i>et al.</i> , "Oligonucleotide Conjugates: Alteration of the Pharmacokinetic Properties of Antisense Agents," <i>Nucleosides &amp; Nucleotides</i> 14(3-5):969-973 (1995)	
	A45	MANOHARAN, <i>et al.</i> , "Lipidic Nucleic Acids," <i>Tetrahedron Lett.</i> 36:3651-3654 (1995)	
	A46	MARHSALL, <i>et al.</i> , "Inhibition of human immunodeficiency virus activity by phosphorodithioate oligodeoxycytidine," <i>Proc. Natl. Acad. Sci. USA</i> 89:6265-6269 (1992)	

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	A47	MARSHALL and CARUTHERS, "Phosphorodithioate DNA as a Potential Therapeutic Drug," <i>Science</i> 259:1564-1570 (1993)	
	A48	MATSUKURA et al., "Antisense phosphorothioates as antivirals against human immunodeficiency virus (HIV) and hepatitis B virus (HBV)." <i>Toxicology Letters</i> , 82/83: 435-538, 1995.	
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	A52	MIYAO, et al., "Stability and Pharmacokinetic Characteristics of Oligonucleotides Modified at Terminal Linkages in Mice," <i>Antisense Res. &amp; Dev.</i> 5:115-121 (1995)	
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				Filing Date	09/12/2003
				First Named Inventor	Andrew Vaillant et al.
				Group Art Unit	1614
Examiner Name					
Sheet	8	of	13	Attorney Docket Number	029849-0206

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	A55	MURANISHI, S., "Absorption Enhancers," <i>Crit. Rev. in Ther. Drug Carr. Syst.</i> 7:1-33 (1990)	
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	A63	PEYMAN, <i>et al.</i> , "Inhibition of Viral Growth by Antisense Oligonucleotides Directed against the IE110 and the UL30 mRNA of Herpes Simplex Virus Type-1," <i>Biol. Chem. Hoppe-Seyler</i> 376:195-198 (1995)		
	A64	QI, <i>et al.</i> , "Study on the Inhibitory effect of antisense phosphorothioate oligodeoxynucleotide on coxsackie virus B <sub>3</sub> replication <i>in vitro</i> ," <i>Chinese J Exp. Clin. Virol.</i> 14:253-256 (2000)		
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	A88	WEINER, <i>et al.</i> , "Liposomes: A Novel Topical Delivery System for Pharmaceutical and Cosmetic Applications," <i>Journ. of Drug Targeting</i> 2:405-410 (1994)		
	A89	WU, <i>et al.</i> , "Increased Microvascular Permeability Contributes to Preferential Accumulation of Stealth Liposomes in Tumor Tissue," <i>Cancer Research</i> 53:3765-3770 (1993)		
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	A93	YU, <i>et al.</i> , "Stereo-Enriched Phosphorothioate Oligodeoxynucleotides: Synthesis, Biophysical and Biological Properties," <i>Biorg. &amp; Medicinal Chem.</i> 8:275-284 (2000)		
	A94	ZAMECNIK, <i>et al.</i> , "Inhibition of replication and expression of human T-cell lymphotropic virus type III in cultured cells by exogenous synthetic oligonucleotides complementary to viral RNA," <i>Proc. Natl. Acad. Sci. USA</i> 83:4143-4146 (1986)		

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	A95	ZHOU and HUANG, "Targeted delivery of DNA by liposomes and polymers," <i>Journ. of Controlled Release</i> 19:269-274 (1992)	
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